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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,062	07/19/2001	Anil K. Saksena	IN01157K	9813

24265 7590 10/02/2002

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

WORTMAN, DONNA C

ART UNIT PAPER NUMBER

1648

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,062

Applicant(s)

SAKSENA ET AL.

Examiner

Donna C. Wortman, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Since two claims numbered 29 were originally filed, the second claim 29 and the claims following it have been renumbered in accordance with 37 CFR 1.126.

Accordingly, claims 1-54 are pending and subject to restriction as follows.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

A single compound recited in claims 1-33, 35, 40, 45, 46, 53, and 54. Claims 1-33, 35, 40, 45, 46, 53, and 54 are drawn to a very large number of specific compounds having the general structure of Formula I or of Formula II, classified in class 530, subclass 323.

Should a compound recited in claims 1-33, 35, 40, 45, 46, 53 and 54 be elected, Applicant is required to select a specific moiety for each variable that is not uniquely defined, i.e., Applicant is required to select a single compound to be examined, and to identify all claims readable on that compound. This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

A pharmaceutical composition and method of treatment recited in claims 34, 36-39, 41-44, 47, and 49. Claims 34, 36-39, 41-44, 47, and 49 are drawn to a large number of pharmaceutical compositions comprising compounds having the general structure of Formula I or Formula II and methods of treatment using them, classified in class 514, subclass 16.

Should a pharmaceutical composition and method comprising a compound recited in claims 34, 36-39, 41-44, 47, and 49 be elected, Applicant is required to select a specific moiety for each variable that is not uniquely defined, i.e., Applicant is required to select a single composition comprising a single compound and method of use to be examined and to identify all claims readable on that composition. This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each composition is

assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

A method of modulating HCV protease recited in claims 48, 50, 51, and 52. Claims 48, 50, 51 and 52 are drawn to methods using a large number of compounds having the general structure of Formula I or Formula II, classified in class 435, subclass 4+.

Should a method using a compound as recited in claims 48, 50, 51 and 52 be elected, Applicant is required to select a specific moiety for each variable that is not uniquely defined, i.e., Applicant is required to select a single compound to be examined, and to identify all claims readable on that compound. This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

The inventions are distinct, each from the other because of the following reasons:

Each compound is patentably distinct from each of the other compounds since each has a chemical structure that is identifiably different from the others. The compounds of claims 1-33, 35, 40, 45, 46, 53, and 54 are patentably distinct from the pharmaceutical compositions and treatment methods of claims 34, 36-39, 41-44, 47, and 49 and from the methods of claims 48, 50, 51, and 52, because the compounds have both *in vivo* and *in vitro* uses. The *in vivo* treatment methods are patentably distinct from the *in vitro* methods of inhibiting HCV serine protease because each method requires different process steps and has a different goal and outcome.

Because these inventions are distinct for the reasons given above, because the search for a compound and a search for each claimed method is not coextensive with

Art Unit: 1648

the search required for either of the claimed method is not coextensive with the search for the other method, and because the search required for any single compound is separate from the search required for any other claimed compound, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:30-5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Application/Control Number: 09/909,062
Art Unit: 1648

Page 5

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
October 1, 2002